REMARKS

Claims 15-23 are pending. Claim 20 is withdrawn as directed to a non-elected species. Claim 15 has been amended to specify that the treatment is of tumors and the zeolite has an average particle size of about 6 microns or less. Claim 16 has been cancelled. Claims 19, 20 and 22 have been amended to make formatting changes. Accordingly, upon entry of the Preliminary Amendment, claims 15 and 17-23 will be pending and claims 15, 17-19 and 21-23 will be under examination.

35 U.S.C. §112, First Paragraph

The Examiner rejected claims 15-19 and 21-23 under 35 U.S.C. §112, first paragraph, as allegedly not enabled for treating cancers other than lung and colorectal cancer or for administering zeolites having a mean particle size other than 250 nm (0.25μm).

In response, applicant respectfully traverses the Examiner's rejection. Claims 15, 17-19 and 21-23, as amended, provide a method of treating a tumor in a patient comprising administering to the patient a pharmaceutical composition comprising a zeolite having an average particle size of about 6 microns or less.

The Examiner's rejection is based on two assertions. First, the specification allegedly does not enable one skilled in the art to practice the claimed method with respect to cancers other than lung or colarectal cancer. The Examiner concedes that the claimed method is enabled with respect to these two cancers. Second, the specification allegedly does not enable one skilled in the art to practice the claimed method using zeolites having a size other than 250nm (0.25μm). The Examiner concedes enablement with respect to zeolites of this size. Applicant addresses each of the Examiner's assertions below.

The Treatment of Tumors is Enabled

The Examiner asserts that the examples in the specification fail to provide guidance for treating a cancer generally using zeolite compositions. Noting that the claims as amended provide a method of treating a tumor - rather than cancer generally - applicants disagree.

Example IV at pp. 26-32 of this application clearly demonstrates the anti-tumor effects of zeolite compositions. In relevant part, this Example teaches the use of a zeolite encapsulated salen-manganese complex to treat mice having implanted tumors of 150 mm^3 volume. The implanted tumors included lung adenocarcenoma, breast adenocarcenoma, colorectal tumors and melanomas. The animals were orally treated with the zeolite for four weeks before the treatments' therapeutic effects were measured. At least with respect to the lung, breast and colorectal tumors, complete remission was observed in at least some of the animals. Regarding the animals having melanomas, "[n]o complete remissions were ever observed..." (p. 32, l. 19-20), although the application is silent as to whether partial remission was observed in the afflicted animals as it was with respect to the other tumor types treated.

In the Final Office Action, as well as the January 26, 2007 Office Action, the Examiner asserts that these examples of tumor treatment, taken with the rest of the application, do not provide sufficient guidance for treating other tumors. At page 5, lines 6 and 7 of the January 26, 2007 Office Action, for example, the Examiner states the following in support of this position: "Applicant . . . has not provided sufficient teachings to treat any types of cancer, for example, how to treat a non-tumor type of cancer, e.g., leukemia, and how to treat a brain tumor that is inoperable in which injection of the zeolite is impossible? Cancer encompasses neoplasm with many causes, striking many tissues, and with many different outcomes. Thus the scope of patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification."

In response, applicant first notes that the claimed invention is directed to the treatment of tumors, rather than cancer generally. Thus, the Examiner's remark concerning the treatment of leukemia and other

non-tumor types of cancer is moot. Applicant also notes that satisfying the enablement requirement does *not* require demonstrating the operability of every embodiment of a claimed invention, so long as a representative number of embodiments are enabled. In this case, the Examiner asserts the non-enablement of treating a brain tumor using the claimed method. Assuming - solely for the sake of argument - that the Examiner's assertion is correct, the specification nevertheless provides guidance for practicing a method of treating tumors wherein a representative number of embodiments are enabled (e.g. treating lung, breast and colorectal tumors).

Applicant further notes that after the subject application's priority date, this invention has been used to successfully treat additional types of tumors. In support of this statement, applicant annexes as Exhibit A a copy of Pavelić et al., "Natural Zeolite Clinoptilolite: New Adjuvant in Anticancer Therapy", J. Mol. Med. (2001) 78:708-720 ("Pavelić").

In relevant part, Pavelić teaches the successful treatment of various tumors in dogs using zeolite compositions. Pavelić provides data in Table 2 (p. 716) for the treatment of 14 dogs afflicted with spontaneous tumors. These tumors include prostate adenoccarcinoma, testis tumor, mammary adenocarcinoma, skin adenocarcinoma, carcinoma planocellulare of the skin, carcinoma planocellulare of the tongue, salivary gland hypertrophy and hyperplasia, and lung cancer. The treatment constituted multiple administrations per day of zeolite composition (designated "MZ") for varying periods. The MZ was obtained through mechanical treatment of natural clinoptilolite particles to produce small-sized particles (see, e.g., p. 709, col. 2, 2nd paragraph). Table 2 states the therapeutic effects for each dog treated. In every case, favorable therapeutic effects were observed, ranging from shrinkage of tumor size to tumor disappearance.

The successful zeolite treatment of such a wide array of tumors underscores the notion that based on the subject application and routine skill as of the priority date, one would have been able to treat tumors without undue experimentation.

The Use of Zeolites Under 6μm is Enabled

The Examiner also asserts that the examples in the specification fail to provide guidance for the anti-tumor use of zeolites other than those having a particle size of 250nm (0.25μm). Specifically, the Examiner cites Pavelic (J. Cancer Res. Clin. Oncol., 2002, 128:37-44) as teaching that "despite very potent and catalytic activities, [zeolites'] internal therapeutic applications have been limited due to poor adsorption of *large* micro sized particles into the body and the risk of side effects..." (emphasis added). The Examiner added that the "specification teaches that particles even *larger* than 5 microns will sediment from a suspension" (emphasis added), citing p. 11, last paragraph of the subject specification.

In response, applicant traverses, and points out the following.

First, the amended claims provide a therapeutic method using zeolites having an average particle size of about 6 micros or less.

Second, contrary to the Examiner's remarks, the cited portion of the subject specification does not teach what the Examiner says it does. Rather, p. 11, last paragraph, of the specification teaches that the "preferred average particle size ... is about 6 microns or less, preferably about 0.5 to 5 microns, and more preferably about 1.5 microns." The only mention of sedimentation is as a technique which *can* be used to *remove* particles larger than 5 microns, if desired. Thus, the specification simply teaches the preferred size range recited in the amended claims.

Third, the adverse zeolite properties taught by the Pavelic article, as characterized by the Examiner, relate only to "large" micro sized particles, rather than the smaller sized particles used in the invention as claimed. Thus, the Examiner's concerns regarding zeolite particle size and related adverse effects are obviated by the fact that the claimed invention uses zeolites of about 6 microns or less.

Applicant further notes that as of the priority date, one skilled in the art could have successfully used zeolites of about 6 microns or less to treat tumors, based on the specification and without undue experimentation.

In support of this statement, applicant again directs the Examiner's attention to Pavelić, annexed as Exhibit A and discussed above. The zeolites ("ZM") used by Pavelić to treat tumors in dogs had a broad size range, falling almost entirely within that recited in the amended claims. Figure 1C at p. 712 of Pavelić shows the size distribution curve for the MZ used in the therapeutic experiments. At column 2 of that page, the authors state that "[p]article size analysis of the MZ showed that maximum frequency of particles (approx. 13%) appeared at 1.5 μm with average size of 2.9 μm. In 25% of particles the size was up to 1.5 μm, in 50% up to 2 μm, and in 75% up to 3 μm (Fig. 1C, D)."

Such particle sizes - which behaved successfully in therapy - fall within the claim limit of about 6 microns or less and well above the 0.25 μm size which the Examiner asserts is the only size enabled. In view of the Pavelić reference, and applicant's remarks above, applicant maintains that the specification enables the full range of particle sizes recited in the claims.

Accordingly, applicant respectfully requests withdrawal of the rejection.

If any additional fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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